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ADVANCED CARDIOVASCULAR SYSTEMS, INC.

DEVICES FOR VASCULAR INTERVENTION, INC.

ORIGIN MEDSYSTEMS, INC.

INVENTION DISCLOSURE FORM

Stent

To: Law Division

cc: K.T. Rao

For Legal Department Use Only

Docket No.: 2106

Date Assigned: ACS-53498.

Submitter: Richard Foust, Jeff Ellis, Florencia Lim, Chi Long, Brian Cahill

This is a form for disclosing ideas and inventions to the Guidant Law Division for patent consideration. This form may be used before experimental work has been done. While some of the requested information may not be available at this time, include as much information as you can about the invention. Attach additional sheets if necessary, and sign and date each sheet. Additional information will be requested later.

1. DESCRIPTIVE TITLE OF THE INVENTION

Detachable Inflatable Sheath To Provide Pre-Deployment Stent Security

2. DESCRIPTION AND USE - (a) Describe the invention in as much detail as possible, and include a description of a working prototype, if any. Write your description using reference numerals placed on a drawing. Point out and explain relationship with associated equipment. (b) How is the invention used? (c) How does it relate to present or potential commercial products of the company or others? (d) State the significance of the invention, and any problems it is intended to solve. Please supplement when possible by attaching sketches, engineering drawings, pages from lab books, photographs, and the like.

(a) The functional aim of this device is to provide the interventional cardiologist with absolute confidence in accessing and treating difficult lesions and/or anatomy with no stent movement. This device is applicable to both coronary and peripheral interventions. The key applications and attributes of this device include the following:

- Stent and stent edges will not catch while stent delivery system (SDS) is advanced through a lesion
- Stent and stent edges will not catch while SDS is advanced through a previously deployed stent
- No stent movement while advancing through difficult lesions
- No compromise to deliverability
- Device can be integrated into current SDS platforms
- Device can be E-beam sterilized

(b) Two embodiments are envisioned for this device. Both embodiments utilize a polyurethane sheath which is attached over a stent or SDS. The elastic properties of the polyurethane sheath can be optimized to allow for selective inflation of the sheath when pressurized. In the current embodiments, the sheath inflates at low pressure (<10 atm), allowing for selective rupture and subsequent deployment of the underlying stent.

In one embodiment, the sheath is first scored then placed over the SDS. The sheath is then pre-stretched to enhance breakaway when inflated. The sheath is laser-sealed to the SDS at the distal balloon taper. The proximal end of the sheath is connected to an over-the-wire inflation hub. When pressurized, the sheath and SDS balloon inflate together. At low pressure, the expansion of the SDS balloon causes the overlying sheath to tear away and expose the stent. As the inflation pressure is increased, the stent can be deployed at its nominal pressure.

In a second embodiment, the sheath is scored and pre-stretched over the SDS as described in the first embodiment. The sheath is the laser-sealed to the distal end of the SDS catheter. The proximal end of the sheath is connected to an over-the-wire inflation hub. The sheath is inflated at low pressure until it tears away and exposes the stent. Then the SDS balloon is inflated to its nominal pressure to deploy the stent.

(c) This device is a prototype design that can be used to provide increased stent security on existing SDS platforms.

(d) This device will provide increased stent retention and security on all current and future Guidant SDS platforms. This device will ensure that stent and stent edges will not catch

while the SDS is advanced through a lesion or through a previously deployed stent. This device will also prevent stent movement while the SDS is advanced through tortuous anatomies. Further, the device does not compromise stent deliverability.

3. PROJECTED GENERIC SCOPE - Describe the invention in terms of the broadest generic scope which you expect will be operable (e.g. if a machine or article, describe alternate type and sizes of materials for construction, etc.; if a process, describe alternate manufacturing conditions, etc.).

[Generic scope described in (2)]

4. REFERENCES - (a) Has a literature search been made? (b) List and, if possible, attach copies of all literature, publications, patents, and patent applications of which you are aware relating to the invention. See section in Guidelines for Completing Invention Disclosure Form concerning obligation of disclosure.

(a) No
(b) No literature, publications, patents, or patent applications are known to pertain to this disclosure

5. DISCLOSURE OR USE - (a) Is the invention known to anyone outside of Guidant? (b) Has the invention been used outside Guidant? (c) What is the current stage of development of the invention ? (d) Are there plans to disclose or use the invention outside of Guidant?

(a) Not at the time of the submission of this disclosure
(b) No
(c) Prototyping stage
(d) Yes – prototypes will be evaluated by a physician

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Read and Understood the completed Invention Disclosure Form (not a Submitter)

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Date

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